



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,911	10/31/2003	David A. Gough	041673-2113	2984

30542 7590 07/31/2006

FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
----------	--------------

3735

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,911

Applicant(s)

GOUGH ET AL.

Examiner

Karen E. Toth

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 12-16, 19-26, 29, 30, 35-39, 42-50 and 52-56 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 6, 8-11, 17-23, 27-29, 31-34, 40, 41 and 51 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/15/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claims 1, 2, and 29 are objected to because of the following informalities:

In Claim 1, line 4 discloses "a body." For clarity, it is suggested that this, and the subsequent references in Claim 1, be changed to --a housing--.

In Claim 2, line 3 discloses "a body." For clarity, it is suggested that this, and the subsequent references in Claim 2, be changed to --a housing--.

In Claim 29, line 6 discloses "a body." For clarity, it is suggested that this, and the subsequent references in Claim 29, be changed to --a housing--.

2. Claims 17-23 are objected to as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 states that the confounding phenomenon comprises a concentration of a substance. Claims 17-23, which depend from Claim 15, state that the confounding phenomenon is one of a variety of parameters that are not concentrations. It is not clear whether the confounding phenomena of Claims 17-23 are additional confounding phenomena to be considered in addition to a concentration, or whether Claims 17-23 should individually depend from Claim 3, which establishes the presence of confounding phenomena. For examination purposes, Claims 17-23 will be treated as depending from Claim 3.

3. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 52-55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is a non-statutory abstraction that could be performed by reading or adjusting a signal from any device. There is no physical transformation and no concrete, tangible result.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 3735

7. Claims 1, 3-5/1, 7/1, 12/1, 13/1, 24/1 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 (US Patent Application Publication 2002/0161286) in view of Miller'562 (US Patent 4748562).

Regarding Claim 1, Gerber'286 discloses an analyte sensor comprising a housing (element 600) with two detectors for detecting environmental analyte concentration (elements 612 and 622) (paragraph [0073]); and a signal processing element that receives signals from the detectors and uses said signals to determine the concentration of an analyte in the immediate environment of the detectors (paragraph [0009]). Said signal processing element computes a signal representative of analyte concentration (paragraph [0079]).

Gerber'286 does not disclose the device's signal processing element comprising means for adjusting the detector's signals by applying coefficients in order to compensate for failure, drift, or environmental variations.

Miller'562 teaches a body measurement sensor comprising means for adjusting a signal by applying coefficients to correct for drift (column 3, lines 20-22 and 41-46) in order to obtain a more accurate analyte concentration reading.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the sensor of Gerber'286 with the means for correction of signals to account for drift, as taught by Miller'562, in order to obtain a more accurate analyte concentration reading.

Regarding Claim 3/1, Gerber'286 discloses all the elements of the current invention, as applied to claim 1, except for the presence of a secondary detector that is responsive to confounding phenomena.

Miller'562 further teaches that the device comprises a reference sensor (element 19) so that the accuracy of the primary signal may be verified.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have made the sensor of Gerber'286 with the secondary sensor of Miller'562, in order to verify the accuracy of the primary signals.

Regarding claim 4/1, the signal processing element of Gerber'286 may be used to connect to the secondary detector (as taught in claim 3 above), since it may be used to connect to a plurality of detectors.

Regarding claim 5/1, Gerber'286 in view of Miller'562 discloses all the elements of the current invention, as applied to claim 4/1 above, except for the signal processing means receiving signals representing the magnitude of the confounding phenomenon detected by the secondary detector.

Miller'562 further teaches that the secondary detector may be used to measure the magnitude of the confounding phenomenon (column 3, lines 31-40); the signal representing that magnitude would therefore be sent to the signal processing element so that it may be used for further analysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Gerber'286 in view of Miller'562, and sent signals representing the magnitude of the confounding phenomenon detected by the secondary detector to the signal processing element, as taught by Colvin'108, so that the signals may be used for further analysis.

Art Unit: 3735

Regarding claim 7/1, Gerber'286 in view of Miller'562 discloses all the elements of the current invention except for calibrating the signal adjustment coefficients.

Miller'562 further teaches calibrating the signal adjustment coefficients (column 6, lines 33-35), in order to improve the accuracy of the sensor's readings.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Miller'562, and calibrated the signal adjustment coefficients, as taught by Miller'562, in order to improve the accuracy of the sensor's readings.

Regarding claim 12/1, Gerber'286 further discloses that the sensor is used to take measurements in the tissue of a living organism (paragraph [0043]), such as a human patient (paragraph [0002]).

Regarding Claim 13/1, Gerber'286 further discloses that the analyte being measured may be glucose (paragraph [0001]).

Regarding Claim 24/1, Gerber'286 further discloses that each primary sensor reflects the analyte concentration in its individual cavity (Figure 16).

8. Claims 2, 3-5/2, 7/2, 12/2, 13/2, 24/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Colvin'108 (US Patent Application Publication 2002/0026108).

Regarding Claim 2, Gerber'286 discloses an analyte sensor comprising a housing (element 600) with two detectors for detecting environmental analyte

Art Unit: 3735

concentration (elements 612 and 622) (paragraph [0073]); and a signal processing element that receives signals from the detectors and uses said signals to determine the concentration of an analyte in the immediate environment of the detectors (paragraph [0009]). Said signal processing element computes a signal representative of analyte concentration (paragraph [0079]).

Gerber'286 does not disclose the device's signal processing element comprising means for adjusting the analyte concentration by applying coefficients in order to compensate for failure, drift, or environmental variations.

Colvin'108 teaches an analyte sensor comprising means for correcting results to account for sensor drift or external environmental factors, in order to obtain a more accurate analyte concentration reading (paragraphs [0016] and [0127]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the sensor of Gerber'286 with the means for correction of results to account for signal drift or external factors as taught by Colvin'108, in order to obtain a more accurate analyte concentration reading.

Regarding Claim 3/2, Gerber'286 discloses all the elements of the current invention, as applied to claim 2, except for the presence of a secondary detector that is responsive to confounding phenomena.

Colvin'108 further teaches that the sensor comprises a secondary reference sensor (paragraphs [0015-0016] and [0126-0127]) that is used to detect external factors in order to verify the accuracy of the primary signal.

Art Unit: 3735

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Colvin'108, as taught above, and further included the secondary reference sensor of Colvin'108, in order to detect external factors and verify the accuracy of the primary signal.

Regarding claim 4/2, the signal processing element of Gerber'286 may be used to connect to the secondary detector (as taught in claim 3 above), since it may be used to connect to a plurality of detectors.

Regarding claim 5/2, Gerber'286 in view of Colvin'108 discloses all the elements of the current invention, as applied to claim 4 above, except for the signal processing means receiving signals representing the magnitude of the confounding phenomenon detected by the secondary detector.

Colvin'108 further teaches that the secondary detector may be used to measure the magnitude of the confounding phenomenon (paragraph [0127]); the signal representing that magnitude would therefore be sent to the signal processing element so that it may be used for further analysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Gerber'286 in view of Colvin'108, and sent signals representing the magnitude of the confounding phenomenon detected by the secondary detector to the signal processing element, as taught by Colvin'108, so that the signals may be used for further analysis.

Art Unit: 3735

Regarding claim 7/2, Gerber'286 in view of Colvin'108 discloses all the elements of the current invention, except for calibrating the signal adjustment coefficients.

Colvin'108 further teaches calibrating the signal adjustment coefficients (paragraph [0151]), in order to improve the accuracy of the readings.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Colvin'108, and further calibrated the signal adjustment coefficients, as taught by Colvin'108, in order to improve the accuracy of the readings.

Regarding claim 12/2, Gerber'286 further discloses that the sensor is used to take measurements in the tissue of a living organism (paragraph [0043]), such as a human patient (paragraph [0002]).

Regarding Claim 13/2, Gerber'286 further discloses that the analyte being measured may be glucose (paragraph [0001]).

Regarding Claim 19/2, Gerber'286 discloses all the elements of the current invention, as applied to Claim 3/2 above, except for the confounding phenomenon being temperature.

Colvin'108 further teaches that the sensor comprises a secondary temperature sensor (element 64) to measure the bioenvironment's temperature (paragraph [0095]), in order to account for any analyte concentration errors due to temperature.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of

Art Unit: 3735

Colvin'108, as taught above, and further included the secondary temperature sensor, as taught by Colvin'108, in order to account for any analyte concentration errors due to temperature.

Regarding Claim 24/2, Gerber'286 further discloses that each primary sensor reflects the analyte concentration in its individual cavity (Figure 16).

9. Claim 14/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Miller'562 as applied to claim 1 above, and further in view of Collins'083 (US Patent 6107083).

Gerber'286 and Miller'562 disclose all the elements of the current invention except for the primary detector incorporating glucose oxidase.

Collins'083 teaches a glucose sensor wherein the sensor incorporates glucose oxidase (column 2, lines 15-19), since would be obvious to substitute an electrochemical sensor for an optical sensor, since it is merely one equivalent sensor for another, and an electrochemical analyte sensor inherently uses glucose oxidase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Miller'562, and incorporated glucose oxidase in the sensor as taught by Collins'083, since would be obvious to substitute an electrochemical sensor for an optical sensor, since it is merely one equivalent sensor for another, and an electrochemical analyte sensor inherently uses glucose oxidase.

Art Unit: 3735

10. Claim 14/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Colvin'108 as applied to claim 2 above, and further in view of Collins'083.

Gerber'286 and Colvin'108 disclose all the elements of the current invention except for the primary detector incorporating glucose oxidase.

Collins'083 teaches a glucose sensor wherein the sensor incorporates glucose oxidase (column 2, lines 15-19), since would be obvious to substitute an electrochemical sensor for an optical sensor, since it is merely one equivalent sensor for another, and an electrochemical analyte sensor inherently uses glucose oxidase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Colvin'108, and incorporated glucose oxidase in the sensor as taught by Collins'083, since would be obvious to substitute an electrochemical sensor for an optical sensor, since it is merely one equivalent sensor for another, and an electrochemical analyte sensor inherently uses glucose oxidase.

11. Claims 15/1, 16/1, and 20/1 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Miller'562, as applied to claims 1 and 3/1 above, and further in view of Wolff'194 (US Patent Application Publication 2004/0158194).

Art Unit: 3735

Regarding Claim 15/1, Gerber'286 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising a concentration of a substance other than the analyte.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the concentration of a substance other than the analyte (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Miller'562, and used the secondary detector to detect the concentration of a substance other than the analyte measured by the primary detector, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

Regarding Claim 16/1, Gerber'286 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising the concentration of oxygen.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the concentration of oxygen (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Miller'562, and used the secondary detector to detect the concentration of oxygen, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

Art Unit: 3735

Regarding Claim 20/1, Gerber'286 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising a patient's heart rate.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the heart rate of a patient (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Miller'562, and used the secondary detector to detect the heart rate of a patient, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

12. Claims 15/2, 16/2, and 20/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Colvin'108, as applied to claims 2 and 3/2 above, and further in view of Wolff'194.

Regarding Claim 15/2, Gerber'286 in view of Colvin'108 discloses all the elements of the current invention, except for the confounding phenomenon comprising a concentration of a substance other than the analyte.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the concentration of a substance other than the analyte (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Colvin'108, and used the secondary detector to detect the concentration of a substance other than the analyte measured by the primary detector, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

Regarding Claim 16/2, Gerber'286 in view of Colvin'108 discloses all the elements of the current invention, except for the confounding phenomenon comprising the concentration of oxygen.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the concentration of oxygen (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Colvin'108, and used the secondary detector to detect the concentration of oxygen, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

Regarding Claim 20/2, Gerber'286 in view of Colvin'108 discloses all the elements of the current invention, except for the confounding phenomenon comprising a patient's heart rate.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the heart rate of

Art Unit: 3735

a patient (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Colvin'108, and used the secondary detector to detect the heart rate of a patient, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

13. Claim 19/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Miller'562 as applied to claim 3/1 above, and further in view of Michel'623 (US Patent 5695623).

Gerber'286 and Miller'562 disclose all the elements of the current invention except for the confounding phenomenon being temperature.

Michel'623 teaches a glucose sensing device comprising a temperature-sensor (column 2, lines 45-50) in order to account for any dependence of the glucose concentration on temperature.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Miller'562, and incorporated the temperature sensor of Michel'623, in order to account for any dependence of the glucose concentration on temperature.

14. Claim 19/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Colvin'108 as applied to claim 3/2 above, and further in view of Michel'623 (US Patent 5695623).

Gerber'286 and Colvin'108 disclose all the elements of the current invention except for the confounding phenomenon being temperature.

Michel'623 teaches a glucose sensing device comprising a temperature-sensor (column 2, lines 45-50) in order to account for any dependence of the glucose concentration on temperature.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Colvin'108, and incorporated the temperature sensor of Michel'623, in order to account for any dependence of the glucose concentration on temperature.

15. Claim 21/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Miller'562, as applied to claim 3/1 above, and further in view of Sackner'252 (US Patent 6551252).

Gerber'286 and Miller'562 disclose all the elements of the current invention except for the confounding phenomenon being respiratory rate.

Sackner'252 teaches a physiological sensing device comprising a first sensor for sensing glucose levels (column 16, lines 49-54) and a second sensor for sensing respiratory rate (column 11, lines 53-55), in order to learn more about a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Miller'562, and incorporated the respiratory rate sensor of Sackner'252, in order to learn more about a patient's condition.

16. Claim 21/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Colvin'108, as applied to claim 3/2 above, and further in view of Sackner'252

Gerber'286 and Colvin'108 disclose all the elements of the current invention except for the confounding phenomenon being respiratory rate.

Sackner'252 teaches a physiological sensing device comprising a first sensor for sensing glucose levels (column 16, lines 49-54) and a second sensor for sensing respiratory rate (column 11, lines 53-55), in order to learn more about a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Colvin'108, and incorporated the respiratory rate sensor of Sackner'252, in order to learn more about a patient's condition.

17. Claim 22/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Miller'562 as applied to claim 3/1 above, and further in view of Anderson'593 (US Patent Application Publication 2003/0126593).

Gerber'286 and Miller'562 disclose all the elements of the current invention except for the confounding phenomenon being physical activity level.

Anderson'593 teaches an analyte sensor comprising a secondary sensor that detects physical activity as a confounding factor (paragraph [0045]), in order to more accurately monitor the patient's analyte levels.

Art Unit: 3735

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Gerber'286 and Miller'562, and used the secondary detector to detect the physical activity level of the patient, as taught by Anderson'593, in order to more accurately monitor the patient's activity levels.

18. Claim 22/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Colvin'108 as applied to claim 3/2 above, and further in view of Anderson'593.

Gerber'286 and Colvin'108 disclose all the elements of the current invention except for the confounding phenomenon being physical activity level.

Anderson'593 teaches an analyte sensor comprising a secondary sensor that detects physical activity as a confounding factor (paragraph [0045]), in order to more accurately monitor the patient's analyte levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Gerber'286 and Colvin'108, and used the secondary detector to detect the physical activity level of the patient, as taught by Anderson'593, in order to more accurately monitor the patient's activity levels.

19. Claim 23/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Miller'562, as applied to claim 3/1 above, and further in view of Whitehurst'114 (US Patent 6832114).

Art Unit: 3735

Gerber'286 in view of Miller'562 discloses all the elements of the current invention except for the confounding phenomenon comprising muscular activity.

Whitehurst'114 teaches a physiological sensor that is used to measure both analyte concentration and muscular activity (column 14, lines 28-34), so that a patient's condition may be more fully evaluated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Miller'562, and sensed muscular activity as the confounding phenomenon, as taught by Whitehurst'114, so that the patient's condition may be more fully evaluated.

20. Claim 23/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Colvin'108, as applied to claim 3/2 above, and further in view of Whitehurst'114.

Gerber'286 in view of Colvin'108 discloses all the elements of the current invention except for the confounding phenomenon comprising muscular activity.

Whitehurst'114 teaches a physiological sensor that is used to measure both analyte concentration and muscular activity (column 14, lines 28-34), so that a patient's condition may be more fully evaluated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 in view of Colvin'108, and sensed muscular activity as the confounding phenomenon, as taught by Whitehurst'114, so that the patient's condition may be more fully evaluated.

21. Claim 25/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Miller'562 as applied to claim 1 above, and further in view of Gough'355 (US Patent Application Publication 2002/0156355).

Gerber'286 and Miller'562 disclose all the elements of the current invention except for the effective detector radius being between 20 and 200 μm .

Gough'355 teaches an analyte sensor comprising an effective radius of between 20 and 200 μm ($0.003'' = 76.2 \mu\text{m}$) (paragraph [0056]), in order to effectively sample the patient's fluids.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Miller'562, with an effective radius of between 20 and 200 μm , as taught by Gough'355, in order to effectively sample the patient's fluids.

22. Claim 25/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 and Colvin'108 as applied to claim 2 above, and further in view of Gough'355.

Gerber'286 and Colvin'108 disclose all the elements of the current invention except for the effective detector radius being between 20 and 200 μm .

Gough'355 teaches an analyte sensor comprising an effective radius of between 20 and 200 μm ($0.003'' = 76.2 \mu\text{m}$) (paragraph [0056]), in order to effectively sample the patient's fluids.

Art Unit: 3735

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Colvin'108, with an effective radius of between 20 and 200 um, as taught by Gough'355, in order to effectively sample the patient's fluids.

23. Claim 26/1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Miller'562, as applied to claim 1 above, and further in view of Rosenthal'476 (US Patent 5077476).

Gerber'286 in view of Miller'562 discloses all the elements of the current application, except for estimating the concentration of an analyte using detector signals, signal adjustment coefficients, and at least one predetermined formula.

Rosenthal'476 discloses a system for estimating analyte concentration using detector signals, signal adjustment coefficients, and at least one predetermined formula (column 4, lines 37-61), in order to produce an accurate concentration estimate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Miller'562, and estimated analyte concentration using detector signals, signal adjustment coefficients, and at least one predetermined formula, as taught by Rosenthal'476, in order to produce an accurate concentration estimate.

Art Unit: 3735

24. Claim 26/2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Colvin'108, as applied to claim 2 above, and further in view of Rosenthal'476.

Gerber'286 in view of Colvin'108 discloses all the elements of the current application, except for estimating the concentration of an analyte using detector signals, signal adjustment coefficients, and at least one predetermined formula.

Rosenthal'476 discloses a system for estimating analyte concentration using detector signals, signal adjustment coefficients, and at least one predetermined formula (column 4, lines 37-61), in order to produce an accurate concentration estimate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Colvin'108, and estimated analyte concentration using detector signals, signal adjustment coefficients, and at least one predetermined formula, as taught by Rosenthal'476, in order to produce an accurate concentration estimate.

25. Claims 29-30, 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562.

Colvin'108 discloses an analyte concentration sensor (paragraph [0003]) comprising a housing (element 12); at least a primary detector for detection of analyte concentration, and a plurality of secondary detectors for measuring reference properties (paragraph [0170]); and signal processing means for correcting results to account for sensor drift or external environmental factors, in

Art Unit: 3735

order to obtain a more accurate analyte concentration reading (paragraphs [0016] and [0127]).

Colvin'108 does not disclose means for adjusting the detector's signals by applying coefficients in order to compensate for failure, drift, or environmental variations.

Miller'562 teaches a body measurement sensor comprising means for adjusting a signal by applying coefficients to correct for drift (column 3, lines 20-22 and 41-46) in order to obtain a more accurate analyte concentration reading.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the sensor of Colvin'108 with the signal adjustment means of Miller'562 in order to obtain a more accurate analyte concentration reading.

Regarding claim 30, Colvin'108 further discloses calibrating the signal adjustment coefficients (paragraph [0151]).

Regarding claim 35, Colvin'108 further discloses that the biological environment comprises human tissue (paragraph [0079]).

Regarding claim 36, Colvin'108 further discloses that the analyte is glucose (paragraph [0079]).

Regarding claim 47, Colvin'108 further discloses that the detector areas do not overlap (see Figure 14).

Art Unit: 3735

26. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562 as applied to claim 29 above, and further in view of Collins'083.

Colvin'108 in view of Miller'562 discloses all the elements of the current invention, except for the primary detector incorporating glucose oxidase.

Collins'083 teaches a glucose sensor wherein the sensor incorporates glucose oxidase (column 2, lines 15-19), since it is well known in the art to use glucose oxidase as a component of an analyte sensor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the sensor of Colvin'108 in view of Miller'562, and included glucose oxidase as a sensor component, as taught by Collins'083, since it is well known in the art to use glucose oxidase as a component of an analyte sensor.

27. Claims 38, 39, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562, as applied to claim 29 above, and further in view of Wolff'194.

Regarding Claim 38, Colvin'108 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising a concentration of a substance other than the analyte.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the

Art Unit: 3735

concentration of a substance other than the analyte (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 in view of Miller'562, and used the secondary detector to detect the concentration of a substance other than the analyte measured by the primary detector, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

Regarding Claim 39, Colvin'108 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising the concentration of oxygen.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the concentration of oxygen (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 in view of Miller'562, and used the secondary detector to detect the concentration of oxygen, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

Regarding Claim 43, Colvin'108 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising a patient's heart rate.

Wolff'562 teaches an apparatus comprising an analyte sensor and a confounding phenomenon sensor that may be used to measure the heart rate of

Art Unit: 3735

a patient (paragraph [0221]), in order to more accurately monitor a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 in view of Miller'562, and used the secondary detector to detect the heart rate of a patient, as taught by Wolff'194, in order to more accurately monitor a patient's condition.

28. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562 as applied to claim 29 above, and further in view of Michel'623.

Colvin'108 in view of Miller'562 discloses all the elements of the current invention, except for the confounding phenomenon comprising temperature.

Michel'623 teaches an analyte sensing device comprising a temperature-sensor (column 2, lines 45-50) in order to account for any dependence of the glucose concentration on temperature.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 in view of Miller'562, and incorporated the temperature sensor of Michel'623, in order to account for any dependence of the glucose concentration on temperature.

29. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562, as applied to claim 29 above, and further in view of Sackner'252.

Art Unit: 3735

Colvin'108 in view of Miller'562 discloses all the elements of the current invention except for the confounding phenomenon being respiratory rate.

Sackner'252 teaches a physiological sensing device comprising a first sensor for sensing glucose levels (column 16, lines 49-54) and a second sensor for sensing respiratory rate (column 11, lines 53-55), in order to learn more about a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 and Colvin'108, and incorporated the respiratory rate sensor of Sackner'252, in order to learn more about a patient's condition.

30. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562 as applied to claim 29 above, and further in view of Anderson'593.

Colvin'108 and Miller'562 disclose all the elements of the current invention except for the confounding phenomenon being physical activity level.

Anderson'593 teaches an analyte sensor comprising a secondary sensor that detects physical activity as a confounding factor (paragraph [0045]), in order to more accurately monitor the patient's analyte levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Colvin'108 and Miller'562, and used the secondary detector to detect the physical activity level of the

Art Unit: 3735

patient, as taught by Anderson'593, in order to more accurately monitor the patient's activity levels.

31. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562, as applied to claim 29 above, and further in view of Whitehurst'114.

Colvin'108 in view of Miller'562 discloses all the elements of the current invention except for the confounding phenomenon comprising muscular activity.

Whitehurst'114 teaches a physiological sensor that is used to measure both analyte concentration and muscular activity (column 14, lines 28-34), so that a patient's condition may be more fully evaluated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 in view of Miller'562, and sensed muscular activity as the confounding phenomenon, as taught by Whitehurst'114, so that the patient's condition may be more fully evaluated.

32. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 and Miller'562 as applied to claim 29 above, and further in view of Gough'355.

Colvin'108 and Miller'562 disclose all the elements of the current invention except for the effective detector radius being between 20 and 200 μm .

Art Unit: 3735

Gough'355 teaches an analyte sensor comprising an effective radius of between 20 and 200 μm ($0.003'' = 76.2 \mu\text{m}$) (paragraph [0056]), in order to effectively sample the patient's fluids.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 and Miller'562, with an effective radius of between 20 and 200 μm , as taught by Gough'355, in order to effectively sample the patient's fluids.

33. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Miller'562, as applied to claim 29 above, and further in view of Rosenthal'476.

Colvin'108 in view of Miller'562 discloses all the elements of the current application, except for estimating the concentration of an analyte using detector signals, signal adjustment coefficients, and at least one predetermined formula.

Rosenthal'476 discloses a system for estimating analyte concentration using detector signals, signal adjustment coefficients, and at least one predetermined formula (column 4, lines 37-61), in order to produce an accurate concentration estimate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 and Miller'562, and estimated analyte concentration using detector signals, signal adjustment coefficients, and at least one predetermined formula, as taught by Rosenthal'476, in order to produce an accurate concentration estimate.

34. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber'286 in view of Collins'083 and Wolff'194.

Regarding Claim 2, Gerber'286 discloses a sensor for determining the concentration of an analyte, such as glucose (paragraph [0001]) comprising a housing (element 600) with two detectors for detecting environmental analyte concentration (elements 612 and 622) (paragraph [0073]). Gerber'286 does not disclose the presence of a secondary detector or a membrane containing immobilized glucose oxidase.

Collins'083 teaches a glucose sensor wherein the sensor incorporates glucose oxidase (column 2, lines 15-19), since it is well known in the art to use glucose oxidase as a component of an analyte sensor.

Wolff'194 teaches a sensing device with a glucose sensor and a secondary detector that produces a signal responsive to oxygen in the device's environment (paragraph [0221]), so that a more complete analysis of a patient's condition may be performed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Gerber'286 with glucose oxidase incorporated in the sensor, as taught by Collins'083, since it's well known in the art as a glucose sensor component, and with a secondary detector to detect

Art Unit: 3735

oxygen, as taught by Wolff'194, so that a more complete analysis of a patient may be performed.

35. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin'108 in view of Collins'083 and Wolff'194

Colvin'108 discloses an analyte concentration sensor (paragraph [0003]) comprising a housing (element 12); at least a primary detector for detection of analyte concentration, and a plurality of secondary detectors for measuring reference properties (paragraph [0170]); and signal processing means for correcting results to account for sensor drift or external environmental factors, in order to obtain a more accurate analyte concentration reading (paragraphs [0016] and [0127]). Colvin'108 also discloses that the sensor may be used to measure glucose (paragraph [0079]). Colvin'108 does not disclose a membrane containing immobilized glucose oxidase, or using the plurality of secondary detectors to detect oxygen in their environment.

Collins'083 teaches a glucose sensor wherein the sensor incorporates glucose oxidase (column 2, lines 15-19), since it is well known in the art to use glucose oxidase as a component of an analyte sensor.

Wolff'194 teaches a sensing device with a glucose sensor and a secondary detector that produces a signal responsive to oxygen in the device's environment (paragraph [0221]), so that a more complete analysis of a patient's condition may be performed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Colvin'108 with glucose oxidase incorporated in the sensor, as taught by Collins'083, since it's well known in the art as a glucose sensor component, and used a secondary detector to detect oxygen, as taught by Wolff 194, so that a more complete analysis of a patient may be performed.

Allowable Subject Matter

36. Claims 6, 8-11, 17-18, 27-28, 31-34, 40-41, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

37. Regarding claims 6, 10, and 11, the prior art of record fails to teach or make obvious the structure, including, *inter-alia*, application of signal adjustment coefficients to a secondary composite signal.

38. Regarding claims 8, 27, 31, 33, and 50, the prior art of record fails to anticipate or make obvious the structure, including, *inter-alia*, signal adjustment through weighting factors.

39. Regarding claims 9, 28, 32, 34, and 51, the prior art of record fails to anticipate or make obvious the structure, including, *inter-alia*, signal adjustment through temporal factors.

40. Regarding claims 17, 18, 40, and 41, the prior art of record fails to anticipate or make obvious the structure, including, *inter-alia*, measuring perfusion as a confounding factor when also measuring analyte concentration.

Conclusion

41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4746218 to Lord, III, which discloses a method of signal processing to compensate for detector failure.

US Patent Application Publication 2005/0196322 to Truex, which discloses the use of a microprocessor to correct for zero drift, calibration drift, degradation of reagent, and degradation of pyroelectric film.

US Patent 6119208 to Schulman, which discloses a multiple-electrode analyte sensing system

US Patent 5711861 to Ward, which discloses a multiple-electrode analyte sensing system


42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ket


ROBERT L. NASSER
PRIMARY EXAMINER